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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/14/2001

*L*

Please find enclosed and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/879,719

Applicant(s)

Curtis

Examiner

D Ware

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-- Th MAILING DATE of this communication app ars on the cov r sh t with th correspond nc address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/1/94.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Claims 1-27 are presented for examination on the merits.

This application is a divisional of case Serial No. 09/388,239, filed on September 1, 1999, which is now U.S. Patent No. 6,245,555. Further, the application also claims benefits to provisional applications 60/098,701, filed September 1, 1998 and 60/125,656, filed March 22, 1999. It is noted that at page 1, line 1 of the instantly filed specification Applicant has provided this information, with the exception of the status of the divisional case. Applicant is hereby requested to update the status of the divisional case at page 1, line 1 of the specification.

Further, Applicant is requested to inform the examiner as to the status of the drawings with respect to whether such drawings filed in the case are formal or informal drawings. Thus, upon such response the examiner will have the drawings reviewed by the Draftsperson once status has been indicated as formal drawings are filed. Such information would be appreciated by the examiner because it is unclear to the examiner whether the drawings are formal. Note that the Draftsperson will only review drawings which have been indicated by the Applicant as formal drawings.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1-9 are rendered vague and indefinite since in claim 1 the recitation of "the cell suspensions" recited at line 7 lacks antecedent basis. There appears to be only one cell suspension provided in the preceding step, thus, it is unclear how more than one cell suspension can be aerated? It is suggested to change the phrase "the cell suspensions" to --the cell suspension--. Furthermore, the step of "varying at least one of the flow rate of the aerating fluid and the composition of the aerating fluid in response to the detected characteristic" is very uncertain with respect to what type of characteristic is being detected? Also "a flow rate" does not adequately describe how the cell suspension changes in response thereto, in order to possess identifying characteristics of which have not been adequately described in the claims. Thus, the metes and bounds of the claims can not be determined. Also "the composition of the aerating fluid" lacks antecedent basis in the claims. For example, note claim 1 at line 12.

Claims 3 and 6 also lack antecedent basis for the recitation of "the cell suspensions" at line 2, as noted above.

Claims 10-16 are vague since it is unclear whether more than one microorganism is intended in the claims because the preamble of claim 10 recites "microorganisms" but the body of the claim at line 9, of claim 10 recites "a microorganism". Therefore, the metes and bounds of the claims can not be determined. It is suggested to use consistent language and terms in the claims. Also it is unclear whether the liner has attached thereto a culture of cells or microorganism? Claim 11 is unclear with respect to "with a flow rate". What flow rate is being described? Also claim 13 is unclear with respect to "the step of detecting a characteristic".

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What characteristic is being detected? Again these phrases and terms are indefinite for these claims as well as claims 1-9, for the reasons as noted above. Is the characteristic some type of one which can be observed with the naked eye? Is claim 14 referring to "optically detecting" in terms of what can be observed with the naked eye, or is some type of instrument used? Also claims 13 and 15, as well as 14 and 16 appear to be essential duplicates of each other unless "varying the aerating fluid composition" is carried out differently than that of "varying the aerating fluid flow rate". It would appear that varying the aerating flow rate is how the composition is varied? Again the metes and bounds of the claims can not be determined. Also it is suggested to change "culture medium" used in claim 10 to --culture media--.

Claims 17-27 are rendered vague and indefinite for those reasons noted above for claims 10-16 since the preamble recites similar terminology "microorganisms" and at line 7, "a microorganism" is recited. Which is it? More than one microorganism appears to be encompassed by the claimed methods. Also how can the circulating step be carried out when "the first opening" is closed after the step of "closing the first opening"? The metes and bounds of the claims are uncertain. There appears to be steps missing from the claimed method in which to clarify how the method is being carried out. Furthermore, it is unclear what the composition of the aerating fluid is? The metes and bounds are unclear. Also the characteristic of the cell culture is unclear. The characteristics have not been well defined in any of the claimed methods.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Smith et al. (A), hereinafter Smith.

Claims are drawn to methods of culturing cells or microorganisms comprising providing flexible containers, introducing culture media therein, inoculating the culture media to provide a cell suspension and aerating with a fluid having a flow rate and detecting a characteristic of the suspension and varying the flow rate in response to this characteristic. Further, a circulating step is also claimed.

Smith teaches flexible containers and culturing cells or microorganisms therein. The containers are disclosed to include culture media, and furthermore, a circulating step is disclosed. Note the abstract, and columns 1, 2, 6 and 7, all lines.

The claims are identical to the disclosure of Smith and are, therefore, considered to be anticipated by the teachings of the cited reference. However, in the alternative that there is some unidentified claimed characteristic for which provides for some difference then such difference is considered to be so slight as to render the claims obvious over the cited reference. The step of

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varying flow rate as well as identifying a characteristic of the culture are inherent to the teachings of Smith. Clearly the pump taught by Smith provides a flow rate as well as the step of circulating disclosed by Smith clearly teaches a flow rate because in order to circulate a fluid culture media a flow rate is required. Therefore, these process steps are inherent to the culturing disclosed by Smith.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware

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December 10, 2001